

according to the location of the drugstore and in accordance with the area of capacity in the workers of ANVISA. **RESULTS:** There were interviewed 105 consumers in drugstores and 140 workers of ANVISA. When asked about the existence of market regulation of drugs, 51.43% and 87.14% of drug users and employees of ANVISA, respectively, said there is regulation of these products. About the PMC, the knowledge was 20.00% of respondents in pharmacies and 57.86% of the employees of ANVISA. Despite of the relative knowledge of PMC, only 01 of the respondents knew where consumers search the PMC, and the employees of ANVISA, 29 knew the sources of research. Although the poor knowledge on the regulation of prices, 84.76% of consumers interviewed considered this activity exerted by the government as important. **CONCLUSIONS:** Although the population consider important that the prices of medicines are regulated by the government, the knowledge of the regulation is small, even on the tools of consumer protection.

PHP121

INSPECTION OF THE PHARMACEUTICAL COMPANIES IN IRAN BY INSPECTION SOFTWARE

Radmanesh R¹, Nikfar S²

¹Tehran University of Medical Sciences, Faculty of Pharmacy, Tehran, Iran; ²Tehran University of Medical Sciences, Faculty of Pharmacy and Food & Drug Laboratory Research Center, Iran MOH, Tehran, Iran

OBJECTIVES: This study was investigating of costs and consequences of two manual and computerized systems for management of information during 2008–2009 for inspection of pharmaceutical industries in Iranian Drug Regulatory Affairs. **METHODS:** To compute costs of processes following items had been considered: Cost of filling and archiving, data collecting (person-hour), reporting (person-hour), transport, software, hardware (main server computer, pocket computer), stationeries. To evaluate the efficacy following outputs and outcomes was considered: Time of information recovering, ability of ranking, preventing of data missing, capacity building and tracking and monitoring. **RESULTS:** The cost of running the new system is 35,000 US Dollars. Cost of education in new method and conventional are 5000 and 1000 US Dollars respectively. Cost of inspection in computerized management of information system (MIS) is decreased to 250 US Dollars from 600 US Dollars for each inspection process. Alongside capacity of system is increased by arming to fast processing method, time of information recovering diminished to 1 working day instead of 3 days, preventing of data missing from 80% to 95% in new one, tracking and monitoring took 7 working days to applied, but new MIS changed that to 1 working day. Ranking of pharmaceutical industries is now available for Iranian Drug Regulatory Affairs after establishment of new inspection system by computer-based MIS. **CONCLUSIONS:** It seems that beside overhead cost of new computerized system that is more than conventional method; considering capacity building; due to decreasing the cost of inspection and increasing of outputs and outcomes indicators, the new system is more efficient.

PHP122

COMPETITIVENESS OF HUNGARY IN INTERNATIONAL CLINICAL TRIALS

Kalo Z¹, Kovacs G², Nagyjanosi L², Nagystok S²

¹Eötvös Loránd University, Budapest, Hungary; ²Syreon Research Institute, Budapest, Hungary **OBJECTIVES:** Patients, health service providers, payers and the society also gain from intensive clinical trial participation, however the majority of benefits are intangible. According to a recent survey Hungary generates 0.15% of the GDP from clinical trials and related activities, therefore the economic importance of this area is acknowledged by the Hungarian government. The clinical trial activity is traditionally strong in the country, however the growth rate of clinical trials is lower than in other Central-Eastern European countries. Our objective was to explore how Hungary can improve its competitiveness in attracting clinical trials. **METHODS:** We conducted a literature review, searched for publicly available documents and interviewed key stakeholders in Hungary to explore potential fields for intervention. **RESULTS:** We identified seven key target areas for intervention to improve the competitiveness of Hungary in clinical trials: the simplification of legal framework for clinical trial related activities, development of infrastructure at main potential sites, organizational development with special focus on SMOs, the simplification of rules and processes for financing clinical trials, investment into developing databases to support the set-up of clinical trials, and finally the marketing promotion of Hungary and its sites to sponsors of clinical trials. **CONCLUSIONS:** The area of international clinical trials is a very competitive market. Hungary can strengthen its market position, if legislators, competent authorities and management teams of investigational sites—by acknowledging the professional and financial benefits of these studies—support the successful implementation of clinical trials in coordinated actions.

PHP123

PHARMACY NETWORK DEVELOPMENT DURING ECONOMIC TRANSITION IN POLAND

Tuszyska M, Hermanowski TR, Feliksiak H

Medical University of Warsaw, Warsaw, Poland

OBJECTIVES: To analyze the effects of liberalization of regulations, concerning establishment of pharmacies and pharmacy points in Poland after 1989. **METHODS:** The data on the number of pharmacies and pharmacy points, used for the analysis were collected by mail survey completed by all regional pharmaceutical supervision authorities. Population data were sourced from the statistical yearbook of Poland. **RESULTS:**

During economic transition Poland was one of few European Union countries, where the number of pharmacies was not regulated within a given area. Therefore, their numbers increased rapidly, reaching 12,153 private pharmacies and 1,397 private pharmacy points in 2009. This means that in 2009 one pharmacy served 3,127 people. Before privatization process started in 1989, all retail pharmacies were managed by a state-owned enterprise “Cefarm”. Since then, the regulations have changed and the number of pharmacies started to grow. The main reasons of this trend was a regulation stipulating that permission to establish a pharmacy can be granted to any private or legal person, disregarding professional education of that person. Pharmacy owner was only required to employ a qualified pharmacist, responsible for managing the pharmacy. Another major institutional change was introduced by the Pharmaceutical Law, voted October 10, 1991, which authorized establishment of pharmacy points. In spite of the general trend, in some poor provinces of Poland the number of pharmacies decreased. June 1, 2010, European Court of Justice ruled that the right to own and operate a pharmacy may be reserved exclusively for pharmacists and that demographic or geographic criteria may be used in the process of issuing permits to operate pharmacies. **CONCLUSIONS:** Currently, the Polish Ministry of Health has to propose amendments to the Pharmaceutical Law, implementing the above mentioned criteria.

PHP124

DESCRIPTION OF THE PRICING AND REIMBURSEMENT SYSTEM IN THE CZECH REPUBLIC

Petríkova A¹, Dolezal T², Lamka J³, Klimes J⁴

¹VFU Brno, Brno, Czech Republic; ²Institute for Health Economics and Technology Assessment, Prague, Czech Republic; ³Charles University, Prague, Czech Republic; ⁴Charles University, Hradec Kralove, Czech Republic

OBJECTIVES: To investigate changes realized in the Czech pricing and reimbursement system since January 2008 and to describe the current development of this system. **METHODS:** We described the legal framework defining the Czech system (Act No. 48/1997 Coll. as amended by the Act No. 261/2007 Coll. on Public Health Insurance) as well as evaluation of the current system from the literature and reports provided by the State Institute for Drug Control (SUKL). **RESULTS:** In order to increase transparency according to EU Transparency Directive and to set fairly-defined deadlines the competencies for the pricing and reimbursement system were merged from Ministries of Finances and Ministry of Health (MoH) under one responsible institution—SUKL. The pricing rules were fully changed—the maximum price is set based as the mean value of all available ex-factory prices in the reference countries (Estonia, France, Italy, Lithuania, Hungary, Portugal, Greece and Spain). The reference reimbursement system contains 251 reference groups of therapeutically interchangeable products with similar clinical efficacy and safety (should be updated annually by MoH). Medicinal products included in one reference group have the main common therapeutic indication in the same reimbursement level which is calculated on the basis of retail prices in all EU countries. The cheapest price for equipotent dose is chosen and re-counted according to local pharmacy and wholesaler margins and value added taxes. In compliance with new legislation the pharmacoeconomic criteria (cost-effectiveness evaluation and budget impact analysis) should be taken into account. There is possibility of extra bonus of basic reimbursement for better efficacy, safety, dosing schedule, compliance, etc. **CONCLUSIONS:** The system has gone through dramatic changes in last two years and some aspects are still facing challenges. Although the new system should reassessed all medicines covered in the country till 2008, currently there are only 20% revised (April 2010).

HEALTH CARE USE & POLICY STUDIES – Risk-Sharing/Performance-Based Scheme/Agreements

PHP125

TRENDS IN UK-BASED PATIENT ACCESS SCHEMES: FINANCIAL-BASED VERSUS OUTCOMES-BASED AGREEMENTS

Woods RM, Johnson KI

Complete Market Access, Macclesfield, Cheshire, UK

OBJECTIVES: Whilst patient access schemes (PAS) are not a new concept, they are clearly receiving increasing attention. The first notable PAS, devised to improve access to beta interferons for multiple sclerosis, was an outcomes-based scheme designed to overcome uncertainty in long-term clinical and cost-effectiveness. It is the nature of the uncertainty that drives the design of PAS, but is there a trend towards which schemes are more popular? We analyzed the design of published PAS employed in the UK in order to determine if outcomes-based or financial-based schemes predominate. **METHODS:** Published PAS were identified from health technology assessment websites (e.g. the National Institute for Health and Clinical Excellence and Scottish Medicines Consortium), literature searching of ISPOR conference abstracts, and searching of ‘patient access scheme’ or ‘risk-sharing scheme,’ using internet search engines. PAS identified were categorised as financial-based (price- or volume-based agreements) or outcomes-based schemes. Desk research was performed to identify the preference for each type of scheme, in terms of uptake by UK Primary Care Trusts. **RESULTS:** Seventeen published PAS were identified from the literature search, from 2002 until 2010. Categorization of PAS as financial-based versus outcomes-based showed that schemes were balanced, but favoured financial-based schemes (59% versus 41%, respectively). The uptake of financial-based schemes was found to be higher than outcomes-based schemes due to administrative burden posed by schemes which rely

on the measurement and reporting of clinical outcomes. **CONCLUSIONS:** PAS were pioneered by the beta interferon outcomes-based scheme for multiple sclerosis, 2002. Since then, published UK-based schemes favour price or volume-based schemes, a trend illustrated by two of the three newest schemes published in 2010. The simplicity of financial-based agreements, combined with poor health care system uptake of outcomes-based schemes and the demand for value-based pricing, suggests that this trend is set to continue.

PHP126

PATIENT ACCESS SCHEMES (PAS) IN THE UK COMING OF AGE: WHAT IMPACT WILL THEY HAVE ON OTHER EU COUNTRIES LIKE ITALY?

Kirpelar S, Mallinson M, White R, Gannedahl A

Double Helix Consulting Group, London, UK

OBJECTIVES: Although patient access schemes (PAS) have historically been implemented for high-cost oncology drugs, recent schemes for chronic diseases like rheumatoid arthritis (RA) have been seen in the UK. This study tries to understand how the shift in PAS from being accepted by payers only for short-term oncology drugs to those for chronic diseases like RA in the UK will influence the situation in Italy, where PAS are known to be widespread. **METHODS:** This study used qualitative telephone interviews to analyze trends in the UK (n = 7) and Italy (n = 7). Interviews were conducted in tertiary hospitals as well as local, regional and national level reimbursement authorities involving financial and clinical stakeholders, and key individuals in the implementation of the scheme. Importance of a number of variables affecting new PAS was ranked. **RESULTS:** Budget-holders in both markets were seen to be sceptical about the impact on long-term budgets due to the move towards PAS for chronic conditions. Of the 14 stakeholders interviewed, 9 said that such schemes in chronic conditions might help companies access markets with lesser clinical evidence on the basis of the class-effect of the drugs and the risk-sharing nature of the schemes. Monitoring of the outcomes on implementation was thought to be crucial. **CONCLUSIONS:** In Italy, increase in PAS for chronic diseases will help drug companies bring drugs to the market earlier. On the other hand, the payers will see this as an increased burden on their budgets as it will mean funding longer term treatment. Also, due to recent issues with monitoring of outcomes in PAS in the UK, their future needs re-consideration. This move of PAS towards chronic conditions is expected to increase the impact that post-marketing monitoring will have on market access for expensive 'me-too' drugs in the EU.

PHP127

ADOPTING A FINANCIAL RISK-SHARING SCHEME FOR NEW TECHNOLOGIES ADDED TO THE NATIONAL LIST OF HEALTH SERVICES IN ISRAEL: STAKEHOLDERS' STATED INCENTIVES AND DISINCENTIVES

Hammerman A, Feder-Bubis P, Greenberg D

Ben Gurion University of the Negev, Beer-Sheva, Israel

OBJECTIVES: To explore major stakeholders' incentives and disincentives to adopt a financial risk-sharing mechanism regarding budget-impact estimates of adopting new technologies in the Israeli National List of Health Services (NLHS). According to the proposed scheme, HMOs will be partially compensated by the pharmaceutical and medical device industry if actual use of a technology is substantially higher than what was projected and allocated. On the other hand, HMOs will partially refund the government for budgets allocated to specific technologies that were not fully used. These unused budgets will be used for adopting other technologies in subsequent years. **METHODS:** Using a semi-structured protocol, we interviewed major stakeholders involved in the process of updating the NLHS (N = 31). Interviewees included government officials, senior managers in the country's four HMOs, pharmaceutical industry executives, and health economists. We inquired into the interviewee's view towards our proposed risk-sharing mechanism, and their opinion on the other stakeholders' incentives to accept or object the proposed scheme. **RESULTS:** Our interviews revealed a wide range of incentives, disincentives, and barriers for adopting the risk-sharing mechanism. There was no consensus on what would be the different stakeholders' incentives and disincentives for adopting the proposed mechanism, even within the various stakeholders groups themselves. Most interviewees from the HMOs and the pharmaceutical industry supported the proposed risk-sharing agreement. Among government officials, the Ministry of Finance decision-makers tended to object to the proposed mechanism, while Ministry of Health executives usually supported the scheme, but believed that the pharmaceutical industry will not support this risk-sharing agreement. **CONCLUSIONS:** Since the success of implementing a risk-sharing mechanism depends mainly on its perception as a win-win situation for all stakeholders, we recommend that decision-makers consider the different incentives and disincentives exposed in our interviews, when implementing such a mechanism.

HEALTH CARE USE & POLICY STUDIES – Beyond Drug Interventions

PHP128

THE USE OF HEALTH PROMOTION INITIATIVES BY MUNICIPALITIES IN BELGIUM. A RETROSPECTIVE OBSERVATIONAL STUDY

Verhaeghe N, Barbe T, Annemans L

Ghent University, Ghent, Belgium

OBJECTIVES: Growing attention is currently given to preventive health care. Prevention can decline the appearance of several diseases and as a consequence lead to a

decrease of health care expenses. The aim of this study was to evaluate if municipalities in Belgium currently are using intervention strategies for optimizing the health behavior of citizens. Special attention was given to what extent certain high-risk groups are reached. **METHODS:** The design consisted of a retrospective observational design. The general services or—if existing—the sports services of 570 Belgian cities (308 in the Flanders and 262 in the Walloon region) were invited by e-mail to participate in the study. After the first mailing, another two mailings were performed. The data were collected using an online questionnaire with closed questions. PASW Statistics 18 was used for statistical analysis. **RESULTS:** The response rate in the Flemish region and Walloon region was respectively 57.47% and 16.41%. In Flanders, 94.9% of respondents reported that they organize health promotion initiatives, while in Wallonia this percentage was 65.1%. Most common organized initiatives in the Flanders region were sport (74.4%) and social welfare (46.4%) initiatives. In Wallonia most common initiatives were prevention of disease/vaccination (45.3%) and sport (44%). Both in Flanders and Wallonia, initiatives concerning mental health were little organized. In general, the initiatives aimed at certain high-risk groups such as persons with mental health problems, older and disabled persons were scarce. On the level of municipal policy lack of appropriate financing was reported as the most common barrier for not organizing preventive strategies. **CONCLUSIONS:** On the level of municipal policy reinforcement of the value of preventive strategies concerning health promotion with appropriate financing is required. When organizing preventive initiatives, special attention to reach certain high-risk groups will be needed.

PHP129

ATTITUDES OF HUNGARIAN POPULATION TOWARD CO-PAYMENTS

Baji P¹, Pavlova M², Gulacsi L¹, Groot W²

¹Corvinus University of Budapest, Budapest, Hungary; ²University of Maastricht, Maastricht, The Netherlands

OBJECTIVES: The issue of the introduction of co-payments is a great policy challenge in most of the Central-Eastern European countries. This is also the case in Hungary, where visit fee was introduced for health care services in 2007, and abolished one year later as a result of a referendum. The aim of our study is to identify different types of attitudes towards patient payments, and answer why visit fee was so unpopular among Hungarian population. **METHODS:** 8 focus-group discussions with health care consumers and physicians and 7 in-depth interviews with policy makers were conducted in Hungary during the summer 2009 on the attitude of patient payments in health care. **RESULTS:** Based on the transcripts and questionnaires filled in by all respondents during the focus group discussions and interviews three different groups of attitude were identified. The group of "Supporters" support the introduction of patient payments with the aim of controlling the unnecessary use of services. The group of "Undecided" concern patient payments as an opportunity to provide additional resource for health care system by paying for "extra-better-quality services". "Sceptics" strongly refuse the idea of patient payments mainly referring to ethical issues. Consumers mainly belong to the group of "Undecided", while one part of the physicians belongs to "Supporters", the other part to "Sceptics". Policy makers are all belong to the group of "Supporters". **CONCLUSIONS:** Before the implementation of patient payments, mapping of population's attitude is inevitable. In Hungary the failure of the introduction of visit fee can be explained by different expectations of health care consumers. They are not against to pay for health care services, but expecting better quality of provided services in return.

PHP130

TRENDS IN COST CONTAINMENT MEASURES

Mukku S, Klein Lankhorst E, Edathodu AS

Double Helix Consulting Group, London, UK

OBJECTIVES: In the current economic climate health authorities are finding ways to control spending. A popular measure is the introduction of cost containment strategies for pharmaceuticals to lessen the burden of cost of drugs. The objective of this research was to analyze the importance of different cost containment measures that payers use in selected markets. The research extends to analyze the gaps between the policies on paper and the extent these are interpreted and executed in practice. **METHODS:** Interviews were conducted with payers at the national, regional and local level in selected European and non-European markets. **RESULTS:** All countries utilise different measures to control spending on pharmaceuticals. The measures that are used by markets include: internal therapeutic referencing, international price referencing, generic substitution, risk-sharing agreements, budget caps, profit caps, index pricing, price cuts, rebates and price volume agreements. The critical finding from the research was that although combinations of measures are included in the national and regional policies, in reality their interpretation and execution varies substantially. For example, Spain uses internal referencing and price referencing at the national level, regions apply price discounts and rebates. Similarly, in The Netherlands a preferred drug policy is introduced, which means that health insurers can now choose a preferred drug for reimbursement, which is usually the cheapest option of the reference basket. If the patient does not want this product, they have to pay the full price of the other product. Another European country which has become the recent focus is Germany; where price regulation will become dominant in the near future. There are uncertainties on achievable prices of drugs, one reason being there is lack of sophisticated systems in place that can monitor these measures. **CONCLUSIONS:** There are currently many developments in the area of cost containment of pharmaceuticals which will have a profound effect on the pharmaceutical industry.